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No. 75-361

In the Supreme Court of the United States

OCTOBER TERM, 1975

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, ET AL., APPELLANTS

v.

F. DAVID MATHEWS, SECRETARY OF HEALTH, EDUCATION, AND WELFARE

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS

MOTION TO AFFIRM

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS

MOTION TO AFFIRM

Pursuant to Rule 16(1)(c) of the Rules of this Court, appellee moves to affirm the judgment of the district court.

STATEMENT

1. In order to improve the quality of medical services rendered to beneficiaries of the Medicare and Medicaid programs, and to reduce the costs of those programs, Congress has provided in 42 U.S.C. (Supp.

III) 1320c to 1320c-19 for the creation of Professional Standards Review Organizations (PSROs). Under Section 1320c-7(a) federal funds may not be used to reimburse physicians or other providers of health care services if the services or items for which payment is claimed have been reviewed by a PSRO and that organization, after review by the Secretary of Health, Education, and Welfare, and, if appropriate, judicial review, has found that the services were rendered in an inappropriate or needlessly costly manner, or should not have been rendered at all.

A PSRO is a nonprofit, voluntary organization approved by the Secretary that, whenever possible, includes a substantial proportion of all licensed physicians located in the area to be served. 42 U.S.C. (Supp. III) 1320c-1. The PSRO reviews all health care services and items rendered by or in institutions for which payment may be made under the Medicare and Medicaid programs to determine (1) whether the services or items are or were medically necessary; (2) whether the quality of the services meets professionally recognized standards of health care; and (3) whether the services would be or could have been more appropriately rendered in another (and less expensive) manner. Section 1320c-4(a). This review usually will occur before the services or items have been provided. The PSRO may also elect to review proposed services or treatments prior to elective admissions to a hospital or the commencement of health care services involving extended or costly courses of treatment. Section 1320c-4(a)(2). The review is

guided by professionally developed norms of care, diagnosis or treatment; these norms take into account the typical patterns of practice in the particular region. Section 1320c-5(a). In order to perform its functions, a PSRO will have access to patient records (Section 1320c-4(b)(3)), but this information will be held in confidence and disclosure may be punished by fines or imprisonment. Section 1320c-15.

Under Section 1320c [1] all physicians and other providers of reimbursable medical services must satisfy certain obligations if they desire to participate in the Medicare and Medicaid programs. When arranging, directing or authorizing another person or hospital to provide health care services to a patient, each physician must exercise his professional responsibility with a view to ensuring that the services will be rendered only when and to the extent they are medically necessary and will be of a quality that meets professionally recognized standards of health care. Section 1320c-9(a)(1). If a PSRO finds that a practitioner has failed, in a substantial number of cases, to fulfill these obligations, or has grossly and flagrantly violated any obligation in one or more instances, it will transmit its findings and recommendations to the Secretary. Section 1320c-9(b). If the Secretary agrees that there has been a failure to fulfill an obligation, he may suspend the practitioner from participation in the Medicare and Medicaid programs

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[1] For the sake of convenience, Sections 1320c to 1320c-19 will occasionally be referred to collectively as "Section 1320c."

(Section 1320c-9(b)(1)) or require the physician to repay the actual or estimated cost of the medically improper or unnecessary services. Section 1320c-9(b)(3). A determination by the Secretary under this provision of the legislation is subject to all the procedural protections contained in the Social Security Act, including judicial review. Section 1320c-9(b)(4); see 42 U.S.C. 405.

2. Appellants brought suit, contending that Section 1320c is unconstitutional on its face. A three-judge district court was convened. That court, in a thorough opinion (J.S. App. 2a-30a; 395 F. Supp. 125), upheld the constitutionality of the statute.

The court first held that Section 1320c is rationally related to a legitimate governmental purpose (J.S. App. 13a) and that appellants had failed to demonstrate that the legislation arbitrarily or invidiously discriminated against them (J.S. App. 11a-12a). The court therefore rejected appellants' contention that the statute is overbroad (J.S. App. 14a).

The court also held that because a physician remains at liberty to decline to participate in the Medicare and Medicaid programs the legislation does not infringe upon the right to practice medicine (J.S. App. 15a-16a) or constitute an impermissible interference with the doctor-patient relationship (J.S. App. 16a-22a).

Finally, the court rejected appellants' contention that the statute is unconstitutionally vague (J.S. App. 23a-24a). The court noted that the statute does not impose criminal penalties (J.S. App. 24a) and

does not provide for disqualification from practice for noncompliance (*ibid.*). The legislation merely establishes the terms and conditions of reimbursement under the Medicare and Medicaid programs (*ibid.*), the court held; under the circumstances, it supplies sufficiently definite warning of the conduct proscribed (*id.* at 23a).

ARGUMENT

Appellants assail the facial constitutionality of a statute that has yet to be fully implemented. Their facial constitutional arguments can be answered succinctly: patients whose medical care is provided by public funds have no constitutional right to whatever care appellants, using "the highest standards of medical practice" (J.S. 8), may "judge necessary" (*ibid.*), or to obtain that care "from a physician * * * of their choice" (*ibid.*). Congress need not agree to pay for whatever care appellants desire to provide, and can influence both the standard of care and the identity of its provider by prior review no less than by *post hoc* review designed to achieve the same ends. We think no more need be said to demonstrate the facial constitutionality of Section 1320c. Appellants' more specific arguments are based upon speculations about the effects of the statute in practice. But appellants have not challenged the implementation of Section 1320c; no implementing regulations were before the court, and appellants' speculations about the effect of the statute in practice are

premature. Their contentions are, in any event, without merit.

1. Section 1320c prohibits payment under the Medicare and Medicaid programs for services that a committee of a physician's peers, utilizing professionally developed norms of care, diagnosis, and treatment—and taking regional differences into account—has determined to be medically unnecessary, more appropriately rendered on an outpatient basis or in another type of inpatient facility, or inconsistent with professionally recognized standards of quality health care.

The legislation serves two purposes. As appellants admit (J.S. 17), it ensures that payment from public funds is made only for medically necessary, efficiently delivered, quality health care. S. Rep. No. 92-1230, 92d Cong., 2d Sess. 254 (1972). Congress decided that the best way to achieve that end was to review services before they were carried out or all the resources committed. The alternative—to deny payments after a *post hoc* review—entails significant waste of resources and disappointment to physicians and institutions that have rendered services with the expectation of repayment. Congress also desired to improve the quality of health care furnished to the aged and the poor (*ibid.*). This goal, too, can be achieved most effectively by reviewing the proposed care before it is completed; *post hoc* review does little to recompense the aged and the poor for deficient care rendered to them. There can be no doubt that these are legitimate governmental objectives. There can

also be no doubt that the legislation is rationally designed to accomplish these objectives.

The Medicare and Medicaid programs both allow reimbursement only for services rendered by practitioners licensed by the state in which they practice. 42 U.S.C. 1395x(r); 45 C.F.R. 249.10(b)(5). But neither program authorizes payment for *all* services rendered by any licensed physician. From the inception of both programs, Congress and the Secretary have required some form of third-party review of physicians' decisions concerning treatment, in order to ensure that services rendered to beneficiaries are medically necessary and efficiently delivered.[2] See

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[2] Under Part A of Medicare, Congress required each participating provider to establish a peer committee to review hospital admissions and the provision of professional services. 42 U.S.C. 1395x(k); 42 U.S.C. 1395cc(b)(2) and (d); 42 U.S.C. 1395f(a)(3). Excessive payments can be recouped and physicians suspended from the program. Regulations promulgated by the Secretary provide for termination of inpatient hospital benefits where a utilization review committee makes a finding that inpatient services are no longer medically necessary. 20 C.F.R. 405.162. The statute also provides that the Secretary may not enter into an agreement with an intermediary nominated by a provider for the determination of amounts due the provider under the program unless the Secretary finds that the nominee is willing and able to assist providers in the application of safeguards against overutilization. 42 U.S.C. 1395h; 20 C.F.R. 405.660(b).

Under Part B of Medicare, the Secretary is authorized to enter into agreements with insurance carriers for the administration of the program, 42 U.S.C. 1395u, and a regulation promulgated by the Secretary provides that a carrier under contract with the Secretary must reject claims for reimburse-

Mount Sinai Hospital of Greater Miami, Inc. v. *Weinberger*, 517 F.2d 329 (C.A. 5); *Szekely* v. *Florida Medical Association*, 517 F.2d 345 (C.A. 5). The Secretary does not pay for unnecessary or inefficiently delivered services (or, where the Secretary has paid for such services, he seeks recoupment). Since patients play little or no role in determining the nature or scope of treatment prescribed, Congress could not accomplish its legitimate objectives of quality and cost control without providing for governmental or peer review of those who prescribe and render the treatment.

Appellants apparently admit (J.S. 17) that such "output controls" on a "spot basis" are rationally related to a legitimate governmental purpose and are not constitutionally infirm. We submit that there is no constitutional difference between the prior and concurrent review of services by a PSRO, and the subsequent review by methods the constitutionality of which appellants concede. Prior and subsequent review both foster—to greater and lesser degrees—the same legitimate objectives. Both "interfere" to some degree with the "freedom" of the physician to provide and be reimbursed for the treatment of his choice; both "interfere" to some degree with the physician-patient relationship. The interference is, however, a necessary concomitant of the attainment of Congress' objectives; indeed, the major objectives cannot be achieved unless physicians' decisions are affected. Appellants speculate that physician-patient relationships will be disrupted by prior review or too-frequent review by a PSRO. But they did not challenge the Secretary's regulations or the operation of any particular PSRO. Appellants' speculations are not supported by experience under the statute. Accordingly, the district court correctly held that Section 1320c is not unconstitutional on its face. See, *e.g.*, *Weinberger* v. *Salfi*, No. 74-214, decided June 26, 1975; *Richardson* v. *Belcher*, 404 U.S. 78; *Dandridge* v. *Williams*, 397 U.S. 471; *Flemming* v. *Nestor*, 363 U.S. 603.[3]

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ment for services which were not medically necessary. 20 C.F.R. 405.678.

For the parallel Medicaid utilization requirements, see 42 U.S.C. 1396a(30); 45 C.F.R. 250.20.

These utilization review procedures remain in effect until a PSRO is formed within a service area and assumes its duties. 42 U.S.C. (Supp. III) 1320c-2.

[3] *American Medical Association* v. *Weinberger*, C.A. 7, No. 75-1547, decided July 22, 1975, upon which appellants rely (J.S. 10-12), is not to the contrary. That case involved not the facial constitutionality of Section 1320c, but the statutory support for and constitutionality of some of the implementing regulations. The court acknowledged the holding of the three-judge district court in the instant case and wrote (slip op. 4; footnote omitted): "The central issue in this litigation is not the principle of utilization review per se." Moreover, the case was an appeal from the grant of a preliminary injunction; the court of appeals expressly refrained from declaring a view on the merits and held only that, because it was not impossible for the plaintiffs to prevail, the district court had not abused its discretion in issuing a preliminary injunction (slip op. 4, 5-6, 8, 9). Taken in context, the passage quoted by appellants (J.S. 12)—"that plaintiffs could ultimately succeed" (slip op. 9)—means no more than that success is not

2. Apparently recognizing that the judgment of the district court must be affirmed if the constitutionality of Section 1320c is measured against its admittedly legitimate objectives, appellants contend (J.S. 15) that the legislation can be upheld only if it is justified by a compelling interest. This contention is without support.

Section 1320c does not "discriminate" in *any* way, let alone upon nationality or race; its operation does not impinge upon any " 'discrete and insular' minority" (*Graham* v. *Richardson*, 403 U.S. 365, 372) or any politically unpopular group (*Department of Agriculture* v. *Moreno*, 413 U.S. 528, 534). As the court below held (J.S. App. 11a), appellants have failed to support their bare allegation that Section 1320c establishes an invidious discrimination.

Nor does Section 1320c infringe upon a fundamental freedom (J.S. 15). The right to practice medicine is not a "fundamental" right. The practice

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utterly precluded. Judge Swygert, concurring (*ibid.*), was unwilling to venture even that far.

Plaintiffs make much of the fact that the Seventh Circuit in *American Medical Association* remanded for a trial on the merits, contending that they, too, should be entitled to such a trial. But the trial in *American Medical Association* was required, in large part, to ascertain whether the regulations at issue in that case were authorized by the statute, and to allow the Secretary to introduce evidence that would prove that the regulations' effect would be permissible under the statute. There is no question here concerning the statutory authorization for, or actual effect of, the Secretary's regulations; appellants have challenged the statute, not the regulations, and the challenge is to the statute's facial validity, not to its validity as applied.

of medicine can be licensed and regulated by the state (*Dent* v. *West Virginia*, 129 U.S. 114), and a state can proscribe particular forms of treatment by physicians, if the proscription is rationally based. *Doe* v. *Bolton*, 410 U.S. 179, 199. Section 1320c accomplishes such permissible regulation.[4]

Even if the right to practice medicine is "fundamental," Section 1320c does not "infringe" upon it. The Section simply establishes the terms and conditions under which the federal government will reimburse physicians and institutions for services rendered. See J.S. App. 15a; *Rasulis* v. *Weinberger*, 502 F.2d 1006 (C.A. 7); *Szekely* v. *Florida Medical Association, supra; Mount Sinai Hospital of Greater Miami, Inc.* v. *Weinberger, supra; Johnson's Professional Nursing Home* v. *Weinberger*, 490 F.2d 841, 844 (C.A. 5). The Section does not require a physician to prescribe or refrain from prescribing any

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[4] Appellant physicians apparently argue (J.S. 16-17) that once states have granted licenses to practice medicine, no further regulation of that practice is permissible. But the Constitution does not command the federal government to withdraw from matters subject to state regulation. Indeed, under the Supremacy Clause and the Commence Clause, it is the federal government that can preempt state regulation, and not the reverse. The federal government—confronted with needs and objectives that differ from those of the states—need not be satisfied with whatever licensing and regulatory systems states may create. "Once Congress has validly exercised the power it possesses, it is free to proscribe those things made legal, or even commanded, by state authority." *South Terminal Corp.* v. *Environmental Protection Agency*, 504 F.2d 646, 677 (C.A. 1). See also *Federal Power Commission* v. *Natural Gas Pipeline Co.*, 315 U.S. 575, 582.

form of treatment. A physician remains at liberty to decline to participate in the Medicare or Medicaid programs or to forego reimbursement in a particular instance. Accordingly, Congress has not unconstitutionally interfered with the right of a physician to treat his patients in accord with his best clinical judgment.[5] See *Steward Machine Co.* v. *Davis*, 301 U.S. 548.

3. Appellants contend (J.S. 18-21) that Section 1320c is unconstitutionally vague. The district court correctly rejected this contention (J.S. App. 23a-24a), which is, in any event, premature. Unless a statute chills First Amendment freedoms, claims of vagueness must be assessed as the statute is applied, not on its face. *United States* v. *Mazurie*, 419 U.S. 544, 550; *United States* v. *National Dairy Corp.*, 372 U.S. 29, 33, 36. Moreover, any lack of precision in the statutory standard may be cured by a clarifying construction or regulation issued by the agency charged with the enforcement of the statute. See, *e.g.*, *Parker*

[5] Appellants also contend (J.S. 18) that Section 1320c unconstitutionally interferes with the physician-patient relationship. This contention is apparently based upon allegations in the complaint (Complaint III, par. 16) that Section 1320c will expose physicians to conflicts between their best judgment as to treatment and the requirements of the norms established by the PSROs, and that these "conflicts" will have the "collateral effect of undermining the mutual trust and rapport between physicians and their patients that is essential to optimum treatment." *Ibid.* Since the norms have yet to be established, appellants' allegations must be taken to mean that it is inherently impossible to establish norms. The district court properly rejected this contention (J.S. App. 16a-17a).

v. *Levy*, 417 U.S. 733; *Civil Service Commission* v. *National Association of Letter Carriers*, 413 U.S. 548, 575-580; *Seagram & Sons* v. *Hostetter*, 384 U.S. 35; *Jordan* v. *DeGeorge*, 341 U.S. 223; *Yakus* v. *United States*, 321 U.S. 414. The allegedly vague provisions of Section 1320c clearly do not touch upon First Amendment rights. Appellants will have ample opportunity to litigate the alleged vagueness of their obligations once local PSROs are formed, regulations promulgated, and appellants are aggrieved by particular actions of a PSRO.

CONCLUSION

The judgment of the district court should be affirmed.

Respectfully submitted.

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